

ka-ro; 394 FEB 03 1987

REPORT

on the Maximization Test*
for the sensitizing potential of

2,4,6-Trianiilino-p-(carbo-2'-ethyl-
hexyl-1'-oxi)-1,3,5-triazine

in guinea pigs
Project No. 30H200/86

carried out in the Department of
Toxicology of BASF Aktiengesellschaft
6700 Ludwigshafen/Rhein, FRG

This report consists of 13 pages and Annexes

* Method based on OECD Guideline (406) for Testing of Chemicals -
adopted May 12, 1981

Dieses Dokument enthält Betriebs- und Geschäftsgeheimnisse der BASF. Es ist Eigentum der BASF und darf nur zu dem von BASF vorgesehenen Zweck verwendet werden. Jede andere oder darüber hinausgehende Verwendung, Verwertung, Weitergabe, Vervielfältigung oder Veröffentlichung bedarf der Einwilligung der BASF.

This document contains manufacturing and trade secrets of BASF. It is the property of BASF and may be used only for that purpose for which it was intended by BASF. Every other or additional use, exploitation, reproduction, publication or submission to other parties require the written permission of BASF.

Report, maximization test; project No.: 30H200/86

From the Department of Toxicology of BASF Aktiengesellschaft,
Ludwigshafen/Rhein, FRG

Head: Prof. Dr.med. Dr.rer.nat. H.-P. Gelbke

Study director/conduct of
study:

Kieczka, Jan. 30, 1987

.....

Dr.rer.nat. Kieczka

Head of section:

Kirsch Jan. 30, 1987

.....

Dr.med.vet. Kirsch

Report, maximization test; project No.: 30H200/86

CONTENTS

	Page
1. SUMMARY	1
2. REASONS FOR THE DOSES	3
3. MATERIAL AND METHOD	4
3.1. Test substance	4
3.2. Animals	5
3.2.1. Selection of animals	5
3.2.2. Housing conditions	5
3.3. Conduct and aim of the study	8
3.3.1. General	8
3.3.2. Pretest	9
3.3.3. Main test	10
3.3.3.1. Induction	10
3.3.3.2. Challenge	11
3.4. Retention of records	12
4. EVALUATION	13
5. ANNEXES	
5.1. Intradermal induction	
5.2. 1st challenge	
5.3. 2nd challenge	
6. STATEMENT OF THE QAU	

1. SUMMARY

The substance 2,4,6-Triamino-*p*-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine was tested for its sensitizing effect on the skin of the guinea pig in the maximization test based on Magnusson and Kligman.

After intradermal induction distinct erythema and edema were observed at the injection sites of the control animals and the test animals which were applied with Freund's adjuvant/aqua dest. (1 : 1). The injection of the test substance preparation in olive oil DAB 8 resp. in Freund's adjuvant/aqua dest. (1 : 1) also caused distinct erythema and edema. The control animals which were applied with olive oil DAB 8 (vehicle) exhibited distinct erythema.

After percutaneous induction incrustation, partially open (caused by the intradermal induction) was observed in the test animals in addition to distinct erythema and edema. The control animals which were applied with olive oil DAB 8 (vehicle) exhibited the same skin reactions as the test animals.

The number of animals with skin findings after the 1st challenge (19 days after intradermal induction) and after the 2nd challenge (26 days after intradermal induction) is summarized in the following table:

	1st challenge		2nd challenge	
	40% in olive oil DAB 8	olive oil DAB 8 unchanged	40% in olive oil DAB 8	olive oil DAB 8 unchanged
Control group 1	0/10	0/10	0/10	0/10
Control group 2	no application of test substance	0/10	0/10	0/10
Test group	0/20	0/20	0/20	0/20

x/y: number of positive reactions/number of animals tested; readings 48 h after application

Report, maximization test; project No.: 30H200/86

The percutaneous challenges with the 40% test substance preparations in olive oil DAB 8 did not cause any skin reactions either in the control animals or in the test animals.

Under these test conditions and following the results described above 2,4,6-Triamino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine does not have a sensitizing effect on the skin of the guinea pig.

2. REASONS FOR THE DOSES

Pretest

In the preliminary test after two 24-hour percutaneous occlusive applications within 96 hours the minimum irritant concentration was found to be a 60% suspension in olive oil DAB 8 and the maximum non-irritant concentration a 40% suspension in olive oil DAB 8 (48 hours after application).

Applicability: it was possible to inject a 5% test substance preparation in olive oil DAB 8 resp. in Freund's adjuvant/aqua dest. (1 : 1) with a syringe.

The following concentrations for induction and the challenge were selected on the basis of the pretests:

Intradermal induction	5% in olive oil DAB 8 resp. in Freund's adjuvant/aqua dest. (1 : 1) resp. olive oil DAB 8 unchanged.
Percutaneous induction	60% in olive oil DAB 8 resp. olive oil DAB 8 unchanged.
1st challenge	40% in olive oil DAB 8 resp. olive oil DAB 8 unchanged.
2nd challenge	40% in olive oil DAB 8 resp. olive oil DAB 8 unchanged.

Randomization carried out on: Sep. 16, 1986

Beginning of test: Sep. 17, 1986

End of test: Oct. 16, 1986

3. MATERIAL AND METHOD**3.1. Test substance**

Name of substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Substance number: 86/200

Batch No.: 18301/142

Degree of purity: 98%

Characterization: Details on the characterization of the test substance may be found in the study documents.

Physical state/appearance: Powder, white

Homogeneity: guaranteed by shaking

Storage stability at about 8°C: On completion of all tests the stability of the test substance will be verified by a repeated analysis. The result can be obtained from the sponsor (ME/Z).

Stability of the test substance preparation(s): The stability of the test substance in olive oil DAB 8 was confirmed by analysis.

Storage conditions: cooling

Report, maximization test; project No.: 30H200/86

3.2. Animals

3.2.1. Selection of animals

Animal species: Guinea pigs

Reasons for the selection: Guinea pigs are used for the study of the sensitizing effect because their sensitivity to a sensitization of the skin is supposed to be most like that of man. This animal species is the test object acknowledged worldwide for sensitization studies.

Strain/quality: Pirbright White, Dunkin
Hartley HOE DHPK [SPF-LAC] BÜ

Origin: Lippische Versuchstierzucht,
Hagemann GmbH & Co. KG,
D-4923 Extertal 1, FRG

Sex: Female

Body weight at the beginning of the study: 257 - 306 g

Acclimatization period: At least 7 days before the beginning of the study in the laboratory for dermal toxicity

3.2.2. Housing conditions

Air conditions: The animals were housed in fully air-conditioned rooms in which a central air-conditioning system ensured a temperature in the range of 20 - 24°C and a relative humidity in the range of 30 - 70%.

Deviations from these specifications that would have had an adverse effect on the test results did not occur.

Report, maximization test; project No.: 30H200/86

Illumination period: 12 h light (6.00 - 18.00 hours) 12 h darkness (18.00 - 6.00 hours)

Type of cage: Makrolon, type IV

No. of animals per cage: 5

Identification of the animals: Ear tag numbering

Type of diet: Kliba 341.4 mm (Kaninchen-Meerschweinchen-Haltungsdiät) ad libitum

Supplier: Firma Klingentalmühle AG, CH-4303 Kaiseraugst, Switzerland

Watering: Water ad libitum (tap water; about 2 g of ascorbic acid per 10 l water was added to the drinking water twice a week)

Bedding: Granulat Typ 3/4 (staubfrei); SSNIFF

Feed analysis:

The feed used in the study was assayed for contaminants. In view of the aim and duration of the study the contaminants occurring in commercial feed ought not to influence the results.

Drinking water analysis:

The drinking water is regularly assayed for contaminants by the municipal authorities of Frankenthal and the Technical Services of BASF Aktiengesellschaft. In view of the aim and duration of the study there are no special requirements exceeding the specifications of the drinking water.

Analysis of the bedding:

The bedding is regularly assayed for contaminants (chlorinated hydrocarbons, heavy metals). In view of the aim and duration of the study there are no special requirements exceeding the specification of a commercial grade monitored by the manufacturer.

Randomization:

According to Salfi, R.: A Long-Period Random Number Generator with Application to Permutation. Compstat 1974, pp. 28 - 35.

Report, maximization test; project No.: 30H200/86

3.3. Conduct and aim of the study

Based on Magnusson, B. and Kligman, A.M.: The Identification of Contact Allergens by Animal Assay. The Guinea Pig Maximization Test. J. Invest. Dermatol. 52, 268 - 276 (1969).

The maximization test was carried out to assess whether the test substance has a sensitizing potential.

3.3.1. General

Weight check of the individual animals: before intradermal induction and before the end of the study. Clipping of the test animals: if required, about 3 to 5 hours before each reading and before each test substance application at the appropriate application sites.

Clinical examinations: no detailed examinations; check for sick animals and for those showing a deteriorated general state each workday.

Form of application:

- intradermal and percutaneous occlusive

For a detailed assessment of a sensitizing potential the percutaneous application which corresponds to the everyday possibility of exposure was preceded by an intradermal application so that the skin barrier was perforated and thus a possible intensified uptake via injured skin areas was taken into account.

Preparation of the test substance formulations:

- immediately before test substance application with Ultraturrax or with a magnetic stirrer
- Formulations of the test substance were prepared gravimetrically; all concentrations were determined in weight/weight.

Report, maximization test; project No.: 30H200/86

3.3.2. Pretest

Amount applied:

2 x 2 cm filter paper strips were applied to the skin of the flanks under an occlusive dressing. In the case of liquids the test filter paper strip was soaked in the test substance formulation; in the case of solid substances the paper strip was coated with an approx. 0.5 mm thick layer of the test substance formulation; thus, the animals were exposed to about 0.15 g of the test substance formulation.

Exposure period:

The test substance was applied 2 times for 24 hours within a period of 96 hours in order to detect non-specific phenomena that are not caused by a sensitization reaction but could possibly be attributed to a shift in the irritation threshold.

Site of application:

- flank, respective on the same area

Number of test animals:

- 4 per test concentration

Readings:

- about 24 and 48 h after the beginning of application

Assessment of skin findings:

1. Erythema and eschar formation

- a) No erythema = 0
- b) Very slight erythema (barely perceptible) = 1
- c) Well-defined erythema = 2
- d) Moderate to severe erythema = 3
- e) Severe erythema (beet redness) to slight
 eschar formation (injuries in depth) = 4

2. Edema formation

- a) No edema = 0
- b) Very slight edema (barely perceptible) = 1
- c) Slight edema (edges of area well defined by
 definite raising) = 2
- d) Moderate edema (raised approximately 1 mm) = 3
- e) Severe edema (raised more than 1 mm and
 extending beyond the area of exposure) = 4

Abbreviations:

lft = left, rt = right

Report, maximization test; project No.: 30H200/86

3.3.3. Main test

Number of animals per control group 10
Number of animals per test group 20

3.3.3.1. Induction

Intradermal induction:

- 6 intradermal injections in groups of two per animal

Injections for the test group:

- A) front row: 2 injections each of 0.1 ml Freund's adjuvant* without test substance emulsified with water in a ratio of 1 : 1
- B) middle row: 2 injections each of 0.1 ml of the test substance formulation
- C) back row: 2 injections each of 0.1 ml Freund's adjuvant*/water (1 : 1) with test substance

Injections for control groups 1 and 2:

- The animals were given the same injections (A, B, C) but without test substance, only with the formulating agent.

Site of application:

- shoulder

Readings:

- 24 h after the beginning of application

Assessment of the skin findings:

- analogous to the pretest

* Supplier of Freund's adjuvant:
O. Nordwald, D-2000 Hamburg 50, FRG

Report, maximization test; project No.: 30H200/86

Percutaneous induction:

- Percutaneous induction was carried out one week after intradermal induction (Date: Sep. 24, 1986).

Amount applied:

2 x 4 cm filter paper strips were applied to the skin of the shoulder under an occlusive dressing. In the case of solid substances the paper strip was coated with an approx. 0.5 mm thick layer of the 60% test substance formulation in olive oil DAB 8; thus, the animals were exposed to about 0.3 g of the test substance formulation.

- The control groups were treated analogously to the test group but only with the solvent (olive oil DAB 8) without the test substance.

Duration of exposure:

- 48 hours

Site of application:

- shoulder, same area as in the case of the previous intradermal application

Readings:

- about 48 h after the beginning of application

Assessment of skin findings:

- analogous to the pretest

3.3.3.2. Challenge

Test concentration: non-irritant concentration

First challenge about 14 days after percutaneous application, second challenge one week later.

Amount applied:

2 x 2 cm filter paper strips were applied to the skin of the flank under an occlusive dressing. In the case of solid substances the paper strip was coated with an approx. 0.5 mm thick layer of the test substance formulation; thus the animals were exposed to about 0.15 g of the test substance formulation.

Report, maximization test; project No.: 30H200/86

1st challenge:

- treatment of the test group and of control group 1 with the test substance formulation. Additional olive oil DAB 8 was applied as a vehicle. Control group 2 only received the vehicle (olive oil DAB 8).

2nd challenge:

- treatment of the test group and of control groups 1 and 2 with the test substance formulation. Analogous to the 1st challenge olive oil DAB 8 was applied to all animals.

Duration of exposure:

- 24 hours

Site of application:

- intact clipped flank

Readings:

- about 24, 48 and 72 h after the beginning of application

Assessment of skin findings:

- analogous to the pretest

3.4. Retention of records

The raw data, reserve samples and original of the protocol, like the original of this report, are retained at BASF Aktiengesellschaft at least for the period of time specified in the GLP regulations.

QAU checked that the test was carried out in accordance with GLP.

Report, maximization test; project No.: 30H200/86

4. **EVALUATION**

(Based on the criteria of Annex VI/II D of the Council Directive of July 29, 1983 for the 5th Amendment of the Directive 67/548 EEC (= 83/467 EEC))

The number of animals sensitized is primarily taken into account in the evaluation. The control animals are used to rule out a substance-induced primary skin irritation.

The findings obtained 48 hours after application are taken into account for the determination of the sensitization rate.

The skin findings after the first and second challenge and the body weights are included in the following Annexes:

5. **ANNEXES**

5.1. Intradermal induction

5.2. 1st challenge

5.3. 2nd challenge

(Detailed data of the results after intradermal and percutaneous induction may be found in the raw data)

Maximization Test - Intradermal Induction

1st CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Form of application: A) Freund's adjuvant / aqua dest. (1 : 1) B) olive oil DAB 8 C) Freund's adjuvant / aqua dest. (1 : 1)										
Animal No.	211	212	213	214	215	216	217	218	219	220
Weight (g)	283	285	290	276	267	293	274	303	287	290

Application: Sep. 17, 1986

Weight determined: Sep. 17, 1986

Maximization Test - Intradermal Induction

2nd CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Triphenylamino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Form of application: A) Freund's adjuvant / aqua dest. (1 : 1)

B) olive oil DAB 8

C) Freund's adjuvant / aqua dest. (1 : 1)

Animal No.	221	222	223	224	225	226	227	228	229	230
Weight (g)	277	300	298	303	272	300	285	271	296	285

Application: Sep. 17, 1986

Weight determined: Sep. 17, 1986

Maximization Test - Intradermal Induction

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Form of application: A) Freund's adjuvant / aqua dest. (1 : 1)

B) Substance 5% in olive oil DAB 8

C) Substance 5% in A)

Animal No.	231	232	233	234	235	236	237	238	239	240
Weight (g)	289	258	297	288	268	292	298	306	289	301

Application: Sep. 17, 1986

Weight determined: Sep. 17, 1986

Maximization Test - Intradermal Induction

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Form of application: A) Freund's adjuvant / aqua dest. (1 : 1)
B) Substance 5% in olive oil DAB 8
C) Substance 5% in A)

Animal No.	241	242	243	244	245	246	247	248	249	250
Weight (g)	257	267	282	276	284	265	296	293	306	272

Application: Sep. 17, 1986

Weight determined: Sep. 17, 1986

Maximization Test - 1st challenge

1st CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank																					
Form of application: right: 40% in olive oil DAB 8 left: olive oil DAB 8																					
Animal No.	211		212		213		214		215		216		217		218		219 ..		220		
	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	
Finding after 24 h	1/0	0/0	1/0	0/0	0/0	0/0	2/1	1/0	2/1	0/0	2/0	0/0	2/0	0/0	0/0	0/0	1/0	0/0	0/0	0/0	
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	

Application: Oct. 6, 1986

X = erythema
Y = edema

Maximization Test - 1st challenge

2nd CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Left flank										
Form of application: olive oil DAB 8										
Animal No.	221	222	223	224	225	226	227	228	229	230
Finding after 24 h	0/0	0/0	0/0	0/0	0/0	0/0	1/0	0/0	0/0	0/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

Application: Oct. 6, 1986

X/Y

X = erythema

Y = edema

Maximization Test - 1st challenge

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank																					
Form of application: right: 40% in olive oil DAB 8 left: olive oil DAB 8																					
Animal No.	231		232		233		234		235		236		237		238		239		240		
Finding after 24 h	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	
	0/0	0/0	2/1	0/0	1/0	0/0	1/0	0/0	1/0	0/0	3/2	1/0	2/0	0/0	2/1	1/0	2/0	0/0	2/0	1/0	
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	

Application: Oct. 6, 1986

X/Y

X = erythema
Y = edema

Maximization Test - 1st challenge

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianiilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank Form of application: right: 40% in olive oil DAB 8 left: olive oil DAB 8																				
Animal No.	241		242		243		244		245		246		247		248		249		250	
	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft
Finding after 24 h	2/0	0/0	1/0	1/0	2/1	0/0	2/0	0/0	2/1	2/0	0/0	0/0	0/0	0/0	2/1	2/0	1/0	1/0	1/0	1/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

Application: Oct. 6, 1986

X/Y

X = erythema
Y = edema

Maximization Test - 2nd challenge

1st CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank																				
Form of application: right: olive oil DAB 8 left: 40% in olive oil DAB 8																				
Animal No.	211		212		213		214		215		216		217		218		219		220	
Finding after 24 h	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft
	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/0	0/0	0/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Weight (g)	433		459		485		425		430		436		427		484		429		498	

Application: Oct. 13, 1986 -

Weight determined (after 72 h): Oct. 16, 1986

X/Y

X = erythema
Y = edema

Maximization Test - 2nd challenge

2nd CONTROL GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Triamino-*p*-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank																				
Form of application: right: olive oil DAB 8 left: 40% in olive oil DAB 8																				
Animal No.	221		222		223		224		225		226		227		228		229		230	
Finding after 24 h	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft
	0/0	0/0	0/0	1/0	0/0	2/0	0/0	0/0	1/0	2/1	0/0	0/0	1/0	2/0	0/0	0/0	0/0	0/0	0/0	0/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Weight (g)	445		443		516		501		438		470		458		421		473		441	

Application: Oct. 13, 1986

Weight determined (after 72 h): Oct. 16, 1986

X/Y

X = erythema
Y = edema

Maximization Test - 2nd challenge

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazine

Right - Left flank Form of application: right: olive oil DAB 8 left: 40% in olive oil DAB 8																				
Animal No.	231		232		233		234		235		236		237		238		239		240	
Finding after 24 h	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft
	0/0	0/0	0/0	0/0	1/0	1/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Weight (g)	477		390		460		446		468		475		514		513		503		474	

Application: Oct. 13, 1986

Weight determined (after 72 h): Oct. 16, 1986

X/Y

X = erythema
Y = edema

Maximization Test - 2nd challenge

TEST GROUP

Project No.: 30H200/86

Name of test substance: 2,4,6-Triamino-1,3,5-triazine

Right - Left flank Form of application: right: olive oil DAB 8 left: 40% in olive oil DAB 8																				
Animal No.	241		242		243		244		245		246		247		248		249		250	
Finding after 24 h	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft	rt	lft
	0/0	2/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	2/0	0/0	0/0
after 48 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
after 72 h	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Weight (g)	456		470		459		465		445		434		457		484		509		423	

Application: Oct. 13, 1986

Weight determined (after 72 h): Oct. 16, 1986

X/Y

X = erythema
Y = edema

6. STATEMENT

of the quality assurance unit

Number of test substance: 86/200

Name of test substance: 2,4,6-Triamylino-p-(carbo-2' -ethyl-
hexyl-1' -oxi)-1,3,5-triazine

Type of study: Maximization test for the sensitizing potential
in guinea pigs

The quality assurance unit inspected the study, audited the final report, and reported findings to the study director and to management.

Date of inspection	Report to study director and to management
Sept. 18, 1986	Oct. 13, 1986
Oct. 13, 1986	Oct. 13, 1986
Jan. 27, 1987	Jan. 28, 1987

Ludwigshafen/Rhein, Febr. 2, 1987


.....
Signature QAU